



2. The remedy for this constitutional violation is an order declaring that Defendants' administrative proceedings are unconstitutional and enjoining such administrative proceedings.

### **PARTIES**

3. Plaintiff Wulferic, LLC d/b/a Vapor Lab is a Texas limited liability company with its principal place of business at 1314 E US Highway 377 # US Granbury, Texas 76048. Plaintiff operates three tobacco retail establishments, including a tobacco retail establishment at 1301 West Henderson Street, Cleburne, Texas 76033.

4. Defendant United States Food and Drug Administration is an executive branch agency of the federal government and is headquartered at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

5. Defendant Robert M. Califf, M.D. (sued here only in his official capacity), is the Commissioner of Food and Drugs and an officer of the United States. His office is at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

6. Defendant United States Department of Health and Human Services ("HHS") is an executive branch agency of the federal government and is headquartered at 200 Independence Avenue, S.W., Washington, DC 20201.

7. Defendant Xavier Becerra, J.D., (sued here only in his official capacity) is the Secretary of Health and Human Services and an officer of the United States. His office is at 200 Independence Avenue, S.W., Washington, DC 20201.

8. FDA is an operating division of HHS. The Commissioner of Food and Drugs reports to the Secretary of Health and Human Services.

### **JURISDICTION AND VENUE**

9. This action arises under the Constitution and laws of the United States. Therefore, the Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1346.

10. Under the Supreme Court’s decision in *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023), the Federal Food, Drug, and Cosmetic Act’s (“FDCA”) statutory review provision for civil money penalties does not displace the Court’s federal question jurisdiction over a constitutional challenge to the FDCA provision that allows civil money penalties to be assessed in an administrative proceeding.

11. The Declaratory Judgment Act authorizes the Court to grant Plaintiff’s request for declaratory relief. 28 U.S.C. §§ 2201-2202.

12. Venue is proper in this district under 28 U.S.C. § 1391(e)(1)(C) because Plaintiff’s principal place of business is in Granbury, Texas.

### **RELEVANT LAW AND FACTS**

#### **A. The Seventh Amendment and *SEC v. Jarkesy*.**

13. The Seventh Amendment to the United States Constitution guarantees a right to a jury in suits “at common law” where the amount at issue exceeds twenty dollars. *See* U.S. Const. amend VII.

14. In *Jarkesy*, 144 S. Ct. 2117, the Supreme Court held that the Seventh Amendment right to a jury trial applies to the Securities Exchange Act’s civil penalties for securities fraud. The Court reasoned that the civil penalties at issue in that case “are designed to punish and deter, not compensate,” and “are therefore ‘a type of remedy at common law that could only be enforced in courts of law.’” *Id.* at 2130 (*quoting Tull v. United States*, 481 U.S. 412, 422 (1987)).

15. In reaching its decision in *Jarkesy*, the Court provided the following analysis:

16. “[T]he Framers used the term ‘common law’ in the [Seventh] Amendment ‘in contradistinction to equity, and admiralty, and maritime jurisprudence.’” *Jarkesy*, 144 S. Ct. at 2128 (quoting *Parsons v. Bedford*, 28 U.S. 433, 446 (1830)). In other words, the Seventh Amendment “embrace[s] all suits which are not of equity or admiralty jurisdiction.” *Jarkesy*, 144 S. Ct. at 2128 (quoting *Parsons*, 28 U.S. at 447).

17. “The Seventh Amendment extends to a particular statutory claim if the claim is ‘legal in nature.’” *Jarkesy*, 144 S. Ct. at 2128 (quoting *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 53 (1989)).

18. “To determine whether a suit is legal in nature,” courts must “consider the cause of action and the remedy it provides.” *Jarkesy*, 144 S. Ct. at 2129. “[T]he remedy” is “the more important consideration.” *Id.* (internal quotation marks and citation omitted.)

19. “While monetary relief can be legal or equitable, money damages are the prototypical common law remedy.” *Id.*

20. “What determines whether a monetary remedy is legal is if it is designed to punish or deter the wrongdoer, or, on the other hand, solely to ‘restore the status quo.’” *Id.* (quoting *Tull*, 481 U.S. at 422).

21. “[A] civil sanction that cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes, is punishment.” *Jarkesy*, 144 S. Ct. at 2129 (quoting *Austin v. United States*, 509 U.S. 602, 610 (1993)).

22. “[W]hile courts of equity could order a defendant to return unjustly obtained funds, only courts of law issued monetary penalties to ‘punish culpable individuals.’” *Jarkesy*, 144 S. Ct. at 2129 (quoting *Tull*, 481 U.S. at 422).

23. “Applying these principles,” the Supreme Court has “recognized that ‘civil penalti[es are] a type of remedy at common law that could only be enforced in courts of law.’” *Jarkesy*, 144 S. Ct. at 2129 (*quoting Tull*, 481 U.S. at 422).

24. The Securities Exchange Act conditions the availability of civil penalties on a variety of factors, several of which “concern culpability, deterrence, and recidivism.” *Jarkesy*, 144 S. Ct. at 2129. “Because [such factors] tie the availability of civil penalties to the perceived need to punish the defendant rather than to restore the victim, such considerations are legal rather than equitable.” *Id.*

25. “The same is true of the [Securities Exchange Act’s] criteria that determine the size of the available remedy.” *Jarkesy*, 144 S. Ct. at 2129. The statute establishes three “tiers” of penalties, with “[e]ach successive tier authoriz[ing] a larger monetary sanction” conditioned “on the culpability of the defendant and the need for deterrence, not the size of the harm that must be remedied.” *Id.* at 2129-30. “Indeed, showing that a victim suffered harm is not even required to advance a defendant from one tier to the next. Since nothing in this analysis turns on restoring the status quo, these factors show that these civil penalties are designed to be punitive.” *Id.* at 2130 (internal quotation marks, brackets and citation omitted).

26. “The final proof that this remedy is punitive is that the SEC is not obligated to return the money to victims.” *Id.* at 2130. “Such a penalty by definition does not ‘restore the status quo’ and can make no pretense of being equitable.” *Id.* at 2130 (*quoting Tull*, 481 U.S. at 422).

**B. *Axon Enterprise, Inc. v. FTC.***

27. In *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023), the Supreme Court held that district courts have jurisdiction to hear constitutional challenges to the Federal Trade Commission’s and the SEC’s processes for adjudicating enforcement actions through administrative law judges (“ALJs”).

28. Both the FTC and the SEC argued that district courts do not have jurisdiction to address constitutional challenges to the administrative enforcement proceedings because the relevant statutes provide that the administrative findings can be challenged in a circuit court. The Supreme Court rejected that argument based on three factors:

29. First, the Court found that precluding a district court challenge to the administrative enforcement proceeding would “foreclose all meaningful judicial review” of the plaintiffs’ claim. *Axon*, 598 U.S. at 186 (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212 (1994)). The Court reasoned that waiting for the circuit court to rule on the constitutional challenge would not provide meaningful judicial review because by that point the plaintiffs would already have suffered their claimed injury—being subjected to an “unconstitutional” proceeding. *Axon*, 598 U.S. at 191.

30. Second, the Court found that the plaintiffs’ claims were “wholly collateral to [the FTC and SEC statutory] review provisions.” *Axon*, 598 U.S. at 186 (quoting *Thunder Basin*, 510 U.S. at 212). The Court reasoned that plaintiffs’ claims were a challenge to the agencies’ constitutional authority to conduct the administrative enforcement actions, not a challenge to the decisions made by the agencies during those administrative proceedings. *Axon*, 598 U.S. at 192-193.

31. Third, the Court found that the plaintiffs’ claims were “outside the [agencies’] expertise.” *Axon*, 598 U.S. at 186 (quoting *Thunder Basin*, 510 U.S. at 212). For example, the Court noted that while agencies like the FTC “know[] a good deal about competition policy,” they

know “nothing special about” issues of constitutional law. *Axon*, 598 U.S. at 194. “For that reason,” the Court had previously observed that ““agency adjudications are generally ill suited to address structural constitutional challenges.”” *Id.* at 194-95 (*quoting Carr v. Saul*, 593 U.S. 83, 92 (2021)).

**C. FDCA Civil Money Penalties.**

32. Section 301(a) of the Food, Drug, and Cosmetic Act (“FDCA”) prohibits the interstate distribution of various of types of “adulterated” and “misbranded” products. *See* 21 U.S.C. § 331(a) (prohibiting “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded”).

33. Persons who violate section 301(a) are subject to criminal prosecution in a district court. *See* 21 U.S.C. § 333(a)(1) (“Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1000, or both.”).

34. The FDCA also authorizes FDA to assess civil money penalties well above \$1,000 against persons for certain violations of section 301(a). *See* 21 U.S.C. § 333(f), (g).

35. However, FDCA civil money penalty cases are not adjudicated in a district court. Instead, they are adjudicated by an ALJ in the Civil Remedies Division of the HHS Departmental Appeals Board (“DAB”). *See* 21 U.S.C. § 333(f)(5)(A); 21 C.F.R. Part 17.

36. As relevant here, the FDCA authorizes an ALJ to assess a civil money penalty of \$15,000 for each violation of section 301(a) with respect to tobacco products, up to \$1,000,000 for all such violations adjudicated in a single proceeding. 21 U.S.C. § 333(f)(9)(A).

37. Similarly to the Securities Exchange Act, the FDCA directs the ALJ to consider factors concerning culpability, deterrence, and recidivism when determining the appropriate amount of a civil money penalty. *See* 21 U.S.C. § 333(f)(5)(B) (listing factors that include the

“gravity of the violation,” the respondent’s “history” of “prior ... violations,” and the respondent’s “degree of culpability”).

38. Indeed, the FDCA also authorizes “enhanced” civil money penalties for certain “intentional” violations with respect to tobacco products. *See* 21 U.S.C. § 333(f)(9)(B)(i) (authorizing a penalty of \$250,000 per violation and additional six-to-seven-figure penalties for violations that continue after FDA provides notice of the violation).<sup>1</sup>

39. An ALJ does not have the authority to find that FDA’s civil money penalty proceedings are unconstitutional. *See* 21 C.F.R. § 17.19(c) (stating the ALJ “does not have the authority to find Federal statutes or regulations invalid”).

40. The ALJ’s decision in a civil money penalty proceeding may be appealed to a panel of three ALJs at the DAB’s Appellate Division. 21 C.F.R. § 17.47.

41. ALJs in the DAB’s Appellate Division do not have the authority to find that the FDA’s civil money penalty proceedings are unconstitutional. 21 C.F.R. § 17.47(g).

42. Any person who is assessed a civil money penalty and loses his appeal at the Appellate Division may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit or in any other circuit in which such person resides or transacts business. 21 U.S.C. § 333(f)(6).

43. All money collected from FDA’s civil money penalty proceedings are “deposited as miscellaneous receipts in the Treasury of the United States.” 21 C.F.R. § 17.54.

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<sup>1</sup> The FDCA’s civil money penalty amounts are adjusted for inflation annually. *See* 45 C.F.R. § 102.3.



**D. FDA’s Administrative Complaint Against Plaintiff.**

44. On September 16, 2024, the FDA’s Center for Tobacco Products (“CTP”) filed an administrative complaint for a civil money penalty of \$20,678 against Vapor Lab in the Civil Remedies Division of the HHS Departmental Appeals Board. (See Exhibit A, Administrative Complaint at ¶ 1).

45. CTP’s Administrative Complaint alleges that on June 29, 2024, an FDA agent conducting an inspection of Vapor Lab’s establishment in Cleburne, Texas observed components used to make e-liquids that Vapor Lab sells at the establishment, and that such e-liquids are “adulterated” and “misbranded” tobacco products because they have not been authorized for sale by FDA and a substantially equivalent report has not been filed for the products. (*Id.* at ¶¶ 17-23).<sup>2</sup>

46. On October 21, 2024, Vapor Lab filed its Answer to the Administrative Complaint. (See Exhibit B, Answer to Administrative Complaint).

47. In its Answer, Vapor Lab stated that it does not waive its Seventh Amendment right to a jury trial and therefore the Seventh Amendment prohibits the Departmental Appeals Board from adjudicating its case. (*Id.* at 2).

48. Vapor Lab also asserted the defenses of unclean hands and selective enforcement because CTP has not sought civil money penalties from “Big Tobacco” companies (*e.g.*, R.J. Reynolds, Altria) for selling “adulterated” tobacco products (electronic cigarettes that have not been authorized for sale by FDA) even though it is undisputed that those companies sell and/or have sold such “adulterated” products. (*Id.*)

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<sup>2</sup> E-liquids are a liquid containing nicotine. Electronic cigarettes heat e-liquids to create a vapor that the user inhales.

49. Finally, Vapor Lab asserted that a civil money penalty of \$20,678 is excessive under the factors specified in 21 U.S.C. § 331(f)(5)(B). Electronic cigarettes are generally considered to be much less harmful than combustible (traditional) cigarettes. Therefore, the sale of an unauthorized vapor products to adults is a much less serious violation of the FDCA than the sale of a combustible cigarettes to minors. However, CTP generally seeks a civil money penalty of only \$345 for the sale of combustible cigarettes to a minor.

50. On October 25, 2024, the ALJ assigned to the proceeding against Vapor Lab in the Civil Remedies Division of the Departmental Appeals Board issued a scheduling order that sets forth deadlines for, among other things, discovery and pre-hearing briefs. (See Exhibit C, Pre-Hearing Order).

**COUNT I**  
**Declaratory and Injunctive Relief on the Ground That  
FDA’s Civil Money Penalty Proceeding Violates the Seventh  
Amendment to the United States Constitution**

51. Pursuant to Federal Rule of Civil Procedure 10(c), Plaintiff Vapor Lab adopts by reference all preceding paragraphs as if fully set forth herein.

52. The Seventh Amendment’s right to a jury trial extends to statutory claims that are “legal in nature.” *Jarkesy*, 144 S. Ct. at 2128.

53. A statutory claim is “legal in nature” when it provides a monetary remedy that “is designed to punish or deter the wrongdoer.” *Id.* at 2129.

54. A monetary remedy “is designed to punish or deter the wrongdoer” when the amount of the monetary remedy is based on factors which “concern culpability, deterrence, and recidivism,” and/or the money collected as a remedy is kept by the government rather than returned to the alleged “victim[s].” *Id.* at 2129.

55. The Seventh Amendment’s right to a jury trial extends to civil money penalties under the FDCA because those penalties are designed to punish or deter the wrongdoer.

56. FDCA civil money penalties are designed to punish or deter the wrongdoer because the amount of the penalties is based on factors which concern culpability, deterrence, and recidivism.

57. FDCA civil money penalties are designed to punish or deter the wrongdoer because the penalties collected by the government are deposited as miscellaneous receipts in the Treasury of the United States.

58. FDA’s civil money penalty proceeding against Vapor Lab violates Vapor Lab’s Seventh Amendment to a jury trial.<sup>3</sup>

59. FDA’s civil money penalty proceeding subjects Vapor Lab to irreparable harm by forcing Vapor Lab to incur the time and expense of an unconstitutional proceeding.

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<sup>3</sup> The dissent in *Jarkesy* argued that the SEC’s civil money penalties fell within the “public rights” exception to the Seventh Amendment as construed in *Atlas Roofing Co. v. Occupational Safety and Health Review Commission*, 430 U.S. 442 (1977). In *Atlas Roofing*, the Court held that the Seventh Amendment did not prevent a federal agency—OSHA—from adjudicating alleged violations of the agency’s workplace safety regulations because such claims were not tried in courts of law prior to the adoption of the Seventh Amendment (1791). *See Atlas*, 430 U.S. at 450. But the majority in *Jarkesy* held that the “public rights” exception did not apply to the SEC’s civil penalties for securities fraud because claims for fraud were being tried in courts of law by the time the Seventh Amendment was adopted. *Jarkesy*, 144 S. Ct. at 2137. Similarly, claims for the sale of “adulterated” products or other violations of the law in the sale of products were being tried in courts of law by the time the Seventh Amendment was adopted. *See, e.g.*, H.W. Schultz, *Food Law Handbook* 2-3 (1981) (noting that in 1785 Massachusetts adopted a statute authorizing the Commonwealth’s Supreme Judicial Court to convict persons for selling any “diseased, corrupted, contagious or unwholesome provisions” and to sentence such persons to “be punished by fine, imprisonment, [and] standing in the pillory”); *McMullen v. City Council of Charleston*, 1 S.C.L. 46 (S.C. Court of Common Pleas 1787) (holding that person charged with selling liquor without a license was entitled to a jury trial); *Phile qui tam v. the Ship Anna*, 1 Dall. 197, 207 (Pennsylvania Court of Common Pleas 1787) (holding that ship owner facing statutory forfeiture of his ship because ship was used to transport goods without paying applicable taxes was entitled to a jury trial). Therefore, *Atlas Roofing* does not apply to FDCA civil money penalties.

60. The FDCA's statutory review provision for civil money penalties does not deprive this Court of jurisdiction to adjudicate Vapor Lab's constitutional challenge to the administrative civil money penalty proceeding because:

a. Requiring Vapor Lab to wait until a circuit court reviews any judgment entered by the HHS Departmental Appeals Board would not provide Vapor Lab with meaningful judicial review because Vapor Lab will already have suffered its claimed injury—the time and expense of an unconstitutional proceeding—by the time the circuit court reviews the judgment;

b. Vapor Lab's claim is collateral to the FDCA statutory review provision because the claim is a constitutional challenge to the administrative proceeding itself, not a challenge to a decision made during that proceeding; and

c. Vapor Lab's claim is outside of HHS's and FDA's expertise. HHS and FDA are public health agencies; they are not agencies with expertise in constitutional law.

#### **REQUEST FOR RELIEF**

61. Plaintiff respectfully requests that this Court enter judgment in its favor that includes the following relief:

a. A declaration pursuant to 28 U.S.C. § 2201 that the FDCA's civil money penalty provisions for tobacco products, 21 U.S.C. § 331(f)(9), violate the Seventh Amendment to the Constitution;

b. A declaration pursuant to 28 U.S.C. § 2201 that the FDA's civil money penalty proceeding against Plaintiff violates the Seventh Amendment to the Constitution;

c. An order requiring the HHS Departmental Appeals Board to dismiss with prejudice the Administrative Complaint against Plaintiff;

d. An order prohibiting HHS and FDA from adjudicating civil money penalties in administrative proceedings;

e. An order prohibiting HHS and FDA from adjudicating civil money penalties against Plaintiff in an administrative proceeding;

f. An order awarding Plaintiff its costs, expenses, and fees (including attorney fees) pursuant to 28 U.S.C. § 2412; and

g. An order granting such further relief as is necessary and appropriate.

Dated: December 3, 2024

Respectfully submitted,

By: /s/ Emily K. Felix

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